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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,927	09/14/2000	William J. Dower	019282-000110US	1158

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EXAMINER
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EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/01/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b> <i>File Copy</i>	Application No.	Applicant(s)	
	09/661,927	DOWER ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2003.
- 2a) ☐ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### SUPPLEMENTAL RESTRICTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. The Response to Restriction Requirement filed on January 9, 2003, is acknowledged (see Paper No. 14).
2. Upon further review of applicants' claims and in further view of applicants' elected species, an additional restriction and/or election was deemed necessary as outlined below.

#### *Election/Restriction*

3. Restriction to one of the following inventions is required under 35 U.S.C. 121. Applicant must elect either Group II or Group IV. **Please note:** that the previous restriction and species election have **NOT** been withdrawn i.e., an **additional** restriction between Group II or Group IV is now required. Groups I and III have only been listed below to preserve the integrity of the record. All traversals will be addressed in the first action on the merits.

I                      Claims 1 (in part), 2-40 and 46-68 drawn to a method for  
                              “screening a carrier-type transport protein.” The invention is  
                              classified variously, for example, in class 436, subclass 501; class

435, subclass 7.1; class 435, DIG 2+ (depending on the type of ligand).

II Claims 1 (in part), 2-40 and 46-68 drawn to a method for “screening a ligand.” The invention is classified variously, for example, in class 436, subclass 501; class 435, subclass 7.1; class 435, DIG 2+ (depending on the type of ligand).

III Claims 1 (in part), 2-40 and 46-68 drawn to a method for “screening a carrier-type transport protein and a ligand.” The invention is classified variously, for example, in class 436, subclass 501; class 435, subclass 7.1; class 435, DIG 2+ (depending on the type of ligand).

IV. Claims 41-45, a method for making a modified complex using the compound identified in Groups I-III above that could be used as a pharmaceutical agent. The invention is classified variously, for example, in class

4. The inventions are distinct, each from the other because of the following reasons:

5. Groups I-III are patentably distinct for the reasons on record (see Paper No. 10, paragraphs 9-10).

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6. Groups I-III and IV represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group IV represents a method of using a compound that was identified in the screening methods of Groups I-III as a potential therapeutic agent i.e., Group IV represents a method of use for the product that is identified in the methods of screening disclosed in Groups I-III. Consequently, the methods produce different result, Furthermore, the method of Group IV requires method steps and reagents that are not required by the methods of Groups I-III e.g., “providing a modified complex” that contains an “agent”. Therefore, Groups I-III and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

8. This application also contains claims directed to additional patentably distinct species as described below. Please note that the previous species election has NOT been withdrawn (see Paper Nos. 10 and 12). The additional species that are required for Group II and Group IV are listed below.

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9. If applicant elects any of the invention of Groups I-IV, applicant is required to elect from the following additional patentably distinct species i.e., select one from each subgroup. Claim 1 is generic.

Subgroup 1: Species of polar moiety (see claims 17-18)

Applicant must elect, for the purposes of search, a single species of polar moiety i.e., applicant must indicate where the polar moiety is in CZ15-73 that reduces passive uptake of the complex (i.e., must show chemical structure for polar moiety with all bonds and atoms described). **Please note:** applicant indicated in Paper No. 15 that claim 18 reads on the elected species, but did not indicate that claim 17 reads on the elected species. The Examiner has interpreted applicants response to include claim 17 because claim 18 cannot read on applicants elected species if claim 17 from which it depends does not.

Subgroup 2: Species of intracellular enzyme (see claim 18)

Applicant must elect, for the purposes of search, a single species of intracellular enzyme.

Subgroup 3: Species of cleavable site (see claims 18 and 58)

Applicant must elect, for the purposes of search, a single species of cleavable site wherein the intracellular enzyme cleaves off the luciferin before the luciferin is metabolized by luciferase (i.e., applicants must show the chemical structure for the cleavage site including all bonds and atoms therein).

Subgroup 4: Species of enzyme (see claim 15)

Applicant must elect, for the purposes of search, a single species of enzyme e.g., luciferase.

Subgroup 5: Species of location for population of cells (see claims 25 and 36)

Applicant must elect, for the purposes of search, a single species of location for population of cells e.g., a single reaction vessel or in different reaction vessels.

Subgroup 6: Species of transformation (see claim 47)

Applicant must elect, for the purposes of search, a single species of transformation indicating whether or not the population of cells has been transformed with a DNA library encoding the elected transport protein i.e., the ileal bile acid transporter (ASBT) (see Paper No. 14).

Subgroup 7: Species of carrier-type protein origin (see claims 51-52)

Applicant must elect, for the purposes of search, a single species of carrier type protein origin e.g., endogenous.

10. If applicant elects the invention of Group IV, applicant is required to elect from the following additional (i.e., the species that applied to Groups I-III also apply to Group IV) patentably distinct species i.e., select one from each subgroup. Claim 41 is generic.

Subgroup 1: Species of modified complex (see claim 41)

Applicant must elect for purposes of search a single species of modified complex. Furthermore, applicant must show all atoms and bonds that are necessary to define said modified complex. Applicant should NOT use general notations like R<sup>1</sup>, R<sup>2</sup>, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

Subgroup 2: Species of compound identified (see claim 41)

Applicant must elect for purposes of search a single species of compound identified. Furthermore, applicant must show all atoms and bonds that are necessary to define said compound identified. Applicant should NOT use general notations like R<sup>1</sup>, R<sup>2</sup>, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

Subgroup 3: Species of agent (see claim 41)

Applicant must elect for purposes of search a single species of agent. Furthermore, applicant must show all atoms and bonds that are necessary to define said agent. Applicant should NOT use general notations like R<sup>1</sup>, R<sup>2</sup>, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Furthermore, applicant must indicate whether said agent is a pharmaceutical agent.

Subgroup 4: Species of reporter (see claim 41)

Applicant must elect for purposes of search a single species of reporter. Furthermore, applicant must show all atoms and bonds that are necessary to define said reporter.

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Applicant should NOT use general notations like  $R^1$ ,  $R^2$ , etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Furthermore, applicant must indicate all points of attachment.

11. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 14 and 15 below).

12. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. **If claims are added after the election, applicant must indicate which are readable upon the elected species.** MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

18. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

19. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an “action on the merits” for purposes of the second action final program, see MPEP 809.02(a).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.  
March 29, 2003

BENNETT CELSA  
PRIMARY EXAMINER

